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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BERCH, MARK L	

ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 05/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/813,954	JAEHNE ET AL.	
	Examiner	Art Unit	
	Mark L. Berch	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) *3-5,11 and 13* is/are withdrawn from consideration.

5)☒ Claim(s) *1,2,7-10 and 12* is/are allowed.

6)☒ Claim(s) *6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *09/23/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-2, 6-10, 12, drawn to Azetidinones, simple compositions and use, classified in class 540, subclass 200.

II. Claims 3-5, drawn to Complex compositions, classified in class 514, subclass various.

III. Claims 11, 13, drawn to Non-heterocyclic intermediates, classified in class 560; 562, subclass 39, 250; 567, 444, 868.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and III are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product, and the species are patentably distinct (MPEP § 806.05(j)). In the instant case, the intermediate product is deemed to be useful as intermediates for making azetidinones where the amide side chain is attached elsewhere and the inventions are deemed patentably distinct because there is nothing on this record to show them to be obvious variants, and because of the marked structural difference between compounds which are and are not heterocycles.

Simple compositions and those with an additional active ingredient are patentably distinct because the combination (complex composition) can be patentable even if the subcombinations (the individual compounds) are not. This is because of the possibility of synergistic interaction, which is usually the purpose of the complex composition in the first place.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Barbara Kurys on 1/4/06 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-2, 6-10, 12. Affirmation of this election must be made by applicant in replying to this Office action. Claims 3-5, 11, 13 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 6 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Disorders of lipid metabolism covers a vast range of very different metabolic problems, These include Wolman's disease; Cerebrotendinous xanthomatosis (an accumulation of cholestanol); sitosterolemia, Refsum's disease (phytanic acid accumulates); Gaucher's disease, which occurs in three different forms (glucocerebrosides accumulate); Niemann-Pick (sphingomyelin accumulates), also in three different forms; Tay-Sachs disease (gangliosides accumulate), Fabry's disease (glycolipids accumulate); Farber disease (which accumulates ceramide); Krabbe Disease (which accumulates psychosine and galactoceramide); Metachromatic Leukodystrophy (sulfatide accumulates); Multiple Sulfatase deficiency (sulfatide and mucopolysaccharides accumulate); Galactosialidosis (no storage product); GM2 gangliosidosis, which exists in three forms (accumulating GM2 ganglioside, GA2 and/or globoside, depending on which form); GM1 gangliosidosis (GM1 gangliosides, glocoproteins, oliosaccharides); Abetalipoproteinemia; hypobetalipoproteinemia; familial ligand-defective Apo-B; hepatic triglyceride lipase (HGTL) deficiency and Cholesterol ester transfer protein (CETP) deficiency. There is also Zellweger, Zellweger-like, Infantile Refsum's disease, adrenoleukodystrophy, and Rhizomelic Chondrodysplasia Punctata which are all peroxisome assembly disorders, although in most cases the primary deficit is unknown. There is also Acyl-CoA deficiency disorder; X-linked adrenoleukodystrophy; bifunctional enxyme deficiency, thiolase deficiency; dihydroxyacetone phosphate acyltransferase (DHAPAT) deficiency; pipecolic academia; Classical Refsum's disease (phytanic acid accumulates); glutaric aciduria Type III; and hyperoxaluria, which are all peroxisome function deficiencies. There are also infantile neuronal ceroid lipofuscinosis. (INCL) and late infantile neuronal ceroid lipofuscinosis (LINCL), both of which can occur in the Finish variant, which are neuronal

ceroid lipofuscinoises. There are also Apo-deficiencies, which come in three types; familial lecithin-cholesterol acyltransferase deficiency and fish-eye disease; and Tangier Disease, all of which involve corneal clouding. There is also lipoprotein lipase deficiency; apolipoprotein C-II deficiency; familial dysbetalipoproteinemia, all of which can cause assorted Xanthomas. There is an entire constellation of fatty acid metabolism disorders. Some are Coenzyme A dehydrogenase deficiencies: Very long-chain acyl-coenzyme A dehydrogenase deficiency (VLCAD); Long-chain 3-hydroxyacyl-coenzyme A dehydrogenase deficiency (LCHAD); Medium-chain acyl-coenzyme A dehydrogenase deficiency (MCAD); Short-chain acyl-coenzyme A dehydrogenase deficiency (SCAD); and Short chain L-3-hydroxyacyl-coA dehydrogenase deficiency (SCHAD). Other Coenzyme A enzyme deficiency disorders include 2,4 Dienoyl-CoA reductase deficiency; 3-hydroxy-3-methylglutaryl-CoA lyase deficiency; and Malonyl-CoA decarboxylase deficiency. The Carnitine related ones are Primary carnitine deficiency; Carnitine-acylcarnitine translocase deficiency; Carnitine palmitoyltransferase I deficiency (CPT); and Carnitine palmitoyltransferase II deficiency (CPT). There are also some miscellaneous one, including Mitochondrial trifunctional protein deficiency; Electron transfer flavoprotein (ETF) dehydrogenase deficiency (also known as GAII or MADD). These vary according to the nature of the storage product (if any), the measured deficiency (which isn't always known), and the genetic defect responsible (which is sometimes also not known). The great majority are totally untreatable per se, and for many even palliative measures are limited or unavailable, and some are fatal in very short order. The notion that any compound could treat these generally is completely inconsistent with the wide range of storage products, enzyme deficiencies and genetic defects involved.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 571-272-0663. The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on (571)272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mark L. Berch
Primary Examiner
Art Unit 1624

5/15/2006